

REMARKS

This Response Under 37 CFR §1.115 is respectfully submitted in response to the Office Action rendered September 23, 2005. It is timely filed in view of the Petition for Extension of Time submitted concurrently herewith. Applicants gratefully acknowledge Examiner Meller's willingness to discuss this application and thank him for taking the time to meet with the undersigned on October 27, 2005.

New claims have been presented in accordance with the discussion held on October 27, 2005 with Examiner Meller. New claims 75-85 find basis in original claims 1-74 and in the Specification at p. 1, l. 1 through p. 7, l. 30.

The Office Action of September 23, 2005 maintained the election of species of record and requested affirmation of the election by applicants. Applicants respectfully submit that the request for affirmation of election of species is moot in view of the cancellation of claims 1-74 and the submission of new claims 75-85.

The Office Action of rejected claims 24 and 28-35 under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. or Ikeda et al. Applicants respectfully request reconsideration of this rejection and respectfully request consideration of new claims 75-85 in view of the ensuing discussion.

Applicants respectfully submit that neither Limkatrul et al. nor Ikeda et al. suggests or discloses the methods of applicants' claimed invention. Limakatrul et al. clearly involves the *ingestion* of soybean milk protein by mice [Limkatrul et al. p. 1]. Thus, the soybean milk protein of Limkatrul et al. must have been capable of being ingested. Further, Ikeda et al. clearly refers to the soybean milk extracts used therein as being available on a "commercial basis" [Ikeda et al. p. 1, 4]. Further, Ikeda et al. discusses "toxicity" as follows: Soybean milk has not exhibited any toxicity whatsoever when consumer as a beverage" [Ikeda et al., p. 4] and requires heating over a hot bath for thirty minutes in preparation of the compositions discussed therein [Ikeda et al., p. 4, 6].

As the applicants noted during the interview that took place on October 27, 2005, soy products containing soybean trypsin inhibitor activity are and were well-known to be dangerous for human ingestion. [See Declaration of Miri Seiberg, ¶2 , attached hereto] Soy products containing such activity can cause gastric distress and even death due to non-absorption of nutrients [Seiberg Declaration, ¶4]. In fact, the World Health Organization

has issued warnings about ingesting uncooked legume products for this very reason [Seiberg Declaration, ¶2]. Thus, any references that indicate that a soy or legume product is ingestible would not have contained active trypsin inhibitors [Seiberg Declaration, ¶2]

The soy products of the compositions of applicants' invention, in contrast, *must* contain active trypsin inhibitors in order to be effective in decreasing phagocytosis or ICAM-1 induction [Seiberg Declaration, ¶4]. As both Limkatrul et al. and Ikeda et al. indicate that the soy products described therein are either ingested [Limkatrul et al.] or non-toxic [Ikeda et al.], neither suggests or discloses the methods of applicants' invention. In view of the foregoing discussion and attached Declaration of Miri Seiberg, applicants respectfully submit that newly-presented claims 75-85 would be patentable in view of Limkatrul et al. and Ikeda et al.

The Office Action of September 23, 2005 further rejected claims 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102(b) as being anticipated by JP 62036304. Applicants respectfully request reconsideration of this rejection with respect to the newly-presented claims and the ensuing discussion.

As discussed at the interview on October 27, 2005, the JP 62036304 reference relates to *ingestible* soymilk as a *cosmetic* treatment. Applicants respectfully attach hereto a copy of the translation of the JP 62036304 reference. Clearly, the soymilk referred to therein is a food product that does not contain active soybean trypsin inhibitor:

The inventors discovered through experimental work that soybeans *not only serve as food products* but that they are also effective in formulations for beauty for external use. In making product containing them on a commercial basis, their extracts...are what is called "soybean milk" ...[JP 62036304, p. 1] (emphasis added)

Furthermore, JP 62036304 refers to the process for producing the soybean milk emulsion, which requires heating, a course of action that denatures and renders *inactive* the trypsin inhibitory proteins in the soybean product. [JP 62036304, p. 2] JP 62036304 also states that "Soybean milk has not exhibited any toxicity whatsoever when consumed as a beverage..." [JP 62036304, p. 4], which clearly indicates that the derivative of soybeans in this reference does not contain soybean trypsin inhibitor.

Moreover, JP 62036304 refers to using soymilk as a "beauty" treatment. It does not indicate that it can be used to treat individuals having an illness that might be treated by applying soybean derivatives.

In view of the foregoing, applicants respectfully request consideration of the newly-presented claims and reconsideration of the rejection under 35 U.S.C. 102(b) based upon JP 62036304.

The Office Action of September 23, 2005 rejected claims 24, 28-36, 38, 44-47 and 58 provisionally under 35 U.S.C. 102(e) as being anticipated by copending Application Serial No. 09/110,409 and 35 U.S.C. 103(a) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application Serial No. 9/110,409. Should claims become granted in the copending patent application, applicants will address the foregoing provisional rejections. As to the rejection under 35 U.S.C. 102(e), Applicants respectfully point out that the claims herein relate to a method of "decreasing phagocytosis or ICAM-1 expression in a patient having one or more of the conditions consisting of pulmonary emphysema, immunological lung disorders, periodontal disease, atherosclerotic plaques, Mid-dermal elastosis, pigmentation disorders, psoriasis, eczema and Acne vulgaris". As discussed during the interview with Examiner Meller on October 27, 2005, Application Serial No. 09/110,409 nowhere describes or suggests such a method. Thus, applicants respectfully submit that Application Serial No. 09/110,409 would not have anticipated the method set forth in the claims of the above-captioned patent application and respectfully request reconsideration of the rejections under 35 U.S.C. 102(e) and 103(a).

The Office Action of September 23, 2005 further rejected claims 24, 28-36, 38, 44-47 and 58 under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. taken with JP 620836304. Claims 24, 28-36, 38, 44-47 and 58 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al. taken with JP 62036304. The Office Action points out that neither Limtrakul et al. nor Ikeda et al. teaches administering soybean milk to a human. The Office Action further states that JP 62036304 "makes it clear that soybean can be administered to a human". [Office Action, p. 7]. Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims and the ensuing discussion.

As pointed out during the interview of October 27, 2005 and hereinabove, JP 62036304 would not have led one of ordinary skill in the art from either Limkatrul et al. or Ikeda et al. to the methods of applicants' invention. As set forth in the accompanying Declaration, soybean plants containing soy trypsin inhibitor are extremely dangerous to human health and can cause disabling or fatal diarrhea [Seiberg Declaration, ¶2]. Thus, publications or patents referring to the oral administration of soy products to a mammal would have required that the soy product be treated so as to denature the protein containing soy trypsin inhibitory activity.

In contrast, the soy products useful in the methods of applicants' invention must contain such activity in order to have the appropriate effect upon the disease states set forth in the claims, and are not suitable for nutritional use. Thus, the Limkatrul et al., Ikeda et al. and JP 62036304 references, taken alone or together, would not have led one of ordinary skill in the art to the methods of applicants' invention. Applicants therefore respectfully request reconsideration of the rejections set forth in the Office Action under 35 U.S.C. 103(a) in view of Limkatrul et al., Ikeda et al. and JP 62036304.

In view of the foregoing, applicants respectfully request reconsideration of the rejections set forth in the Office Action of September 23, 2005. An early allowance is earnestly solicited.

Respectfully submitted,

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